DiaMed GmbH
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Cressier, 24 February 2021

Field Safety Notice / *FSCA 001-21*

Affected products displaying the issue:

Product Name	Id-n	Catalog No	Lot No	Expiry Date
DiaClon Anti-M/N*	51210	006011	51210 10 01 51210 11 01 51210 12 01 51210 12 02 51210 13 02	04.2021 06.2021 09.2021 10.2021 10.2021
DiaClon Anti-N	50221	007111	50221 05 01 50221 06 01 50221 07 01 50221 07 02	04.2021 06.2021 07.2021 09.2021

*The only impacted well of the card is the anti-N. There is no issue with anti-M and ctl well.

Dear Customer,

This letter contains important information that requires your immediate and urgent attention. Bio-Rad is voluntarily conducting a Field Safety Corrective Action for the products identified above.

Description of the problem:

We would like to share information about unexpected reactions that could be observed when using the DiaClon anti-N and DiaClon anti-M/N mentioned above.

Following customer feedback, we confirm that non-specific reactions could be observed in the **anti-N well (MNS2)** of the above-mentioned cards with N negative samples (MNS: -2).

The table 1 shows the range of false positive reactions that may occur.

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Uninterpretable Reaction "+/-"	*False Positive Reaction "+"*	*False Positive Reaction "++"*

Table 1: Example of non-specific reactions obtained on IH-500 with the impacted lots of card

The phenomenon is observed frequently when the ID-Cards are used on the IH-500. It is more rarely observed when the ID-Cards are used on IH-1000 or tested in the manual or semi-automated methods (Saxo ID-Reader II, Banjo ID-Reader, Swing TwinSampler, Classic ID-Gelstation).

Impact on the patient:

Impact on the result	There is a risk of a false positive result (up to 2+ maximum) for the typing of the N antigen when carried out with lot numbers listed above.
Risk in the context of donor typing	None as N positive blood units will not be used for transfusing a patient having a clinically significant anti-N
Risk in the context of patient typing	Delayed result - this antigen typing would be carried out for a patient presenting with a clinically significant anti-N. This inconsistency would lead to further testing.

We advise you to assess this situation with your biologist to determine if retesting is deemed necessary and take the appropriate course of action depending on the patient's clinical conditions, medical history, and other relevant laboratory data.

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Immediate protective measure for the user:

Testing Method	Recommendation
IH-500	1) Stop using the impacted ID-cards on the IH-500. 2) Use one of the following methods: • Manual method or, • semi-automated method or, • fully automated method with the IH-1000 analyzer, according to recommendations described below.
IH-1000 and semi-automated methods	Deactivate the automatic validation of the results in IH-Com In case of a reaction shown as **+/-, +** or **++** by the instrument please follow the recommendations below: 1) Invalidate the result, 2) Repeat the test with the manual method
Manual Method	If visual interpretation of the reaction is **+/-**, **+**, or **++** (refer to table 2): 1) Invalidate the result, 2) Repeat the test If retesting does not permit to conclude the presence or absence of the N antigen, use an alternative method such as an antigen profile determination including an incubation step at room temperature.

Any negative reaction obtained with the impacted lots should be considered as valid and indicates the absence of the corresponding antigen.

Any positive reaction obtained with the impacted lots showing a reaction strength of +++ to ++++ (refer to table 2 or instrument interpretation) should be considered as valid and indicates the presence of the corresponding antigen.

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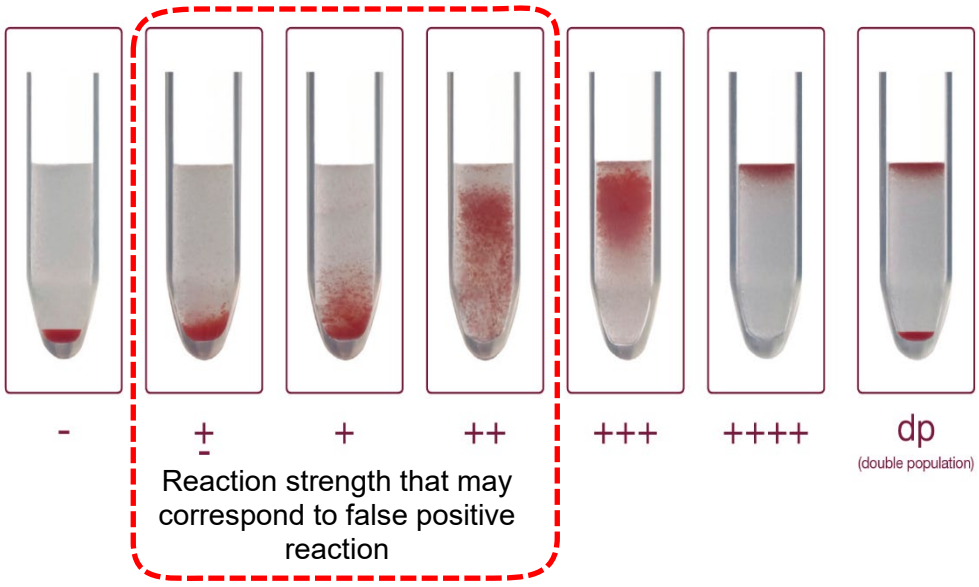

Table 2: Reading charter for visual interpretation of reaction strength

We request you transfer this information to all persons impacted in your institution and/or forward it to all locations where products may have been transferred.

Please note that the relevant European Regulatory Agency has been advised of this Field Safety Corrective Action.

In case of any questions, in the first instance, please contact your local technical support:

[insert local contact information/e-mail address]

Our representatives are briefed to help you manage this situation.

We apologize for any inconvenience that may have been caused by this action and we appreciate your prompt cooperation in this matter.

Yours sincerely,

Quality Assurance Representative	*Marketing Director Immunohematology*
Diane Galéa	Marc Meyer